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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,471	10/19/2001	Martin T. Martin	100391-02030	1031
35745	7590	01/30/2006	EXAMINER	
KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/039,471	Applicant(s) MARTIN, MARTIN T.	
	Examiner Charles L. Patterson, Jr.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-20, 23, 26-29 and 32-45 is/are pending in the application.
4a) Of the above claim(s) 7-9 and 33-45 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3, 6, 10-20, 23, 26-29 and 32 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 19 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

It is noted that applicant's representative states that a new oath or declaration will be submitted as soon as applicant's signature can be obtained.

Claims 7-9 and 33-45 and claims drawn to the invention of Group I not limited to the indicated specie are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/13/04 and 3/2/05.

The amendment filed 11/10/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has changed the previous recitations of "10 g/ml" and "10 g/ml" in columns 2 and 3 of Table 2 to "10 μ M" and "100 μ M", respectively, with the only explanation being that "applicant has amended Table 2 to correct a typographical error". This is no explanation as to why these changes were made and therefore it is deemed to be new matter until proven otherwise by applicant. "10 g/ml" is not the same as "10 μ M", which is defined as 10 μ moles of the antibiotic per liter. Exactly what a mole is depends upon the molecular weight of the particular antibiotic. Changing "10" to "100" in the second column is a ten fold change with absolutely no explan-

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ation as to why this was done. Are the changes perhaps related to some recitations in the rest of the specification?

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 1, 15, 17-18 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 17 and 27 are indefinite and confusing in that they do not properly state a Markush group. MPEP 2173.05(h) states that Markush groups can be expressed as "selecting from the group consisting of A, B and C" or else "wherein R is A, B, C or D". The instant recitation does not contain the words "and" or "or" and therefore are confusing.

Claim 15 is indefinite in the recitation of "said on or more β -lactam antibodies", which has no antecedent basis.

Claim 18 is incorrect in that it does not end with a period.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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This rejection is repeated for the reasons given in the last action. Applicant's arguments have been carefully considered but do not overcome the instant rejection.

Applicant argues that the specification teaches a much broader enablement than the addition of a β -lactam antibiotic to a biologically active molecule by panning phages. As previously stated, while the specification has many general discussions about antibiotic resistance, the characteristics of various biologically active proteins and various models for analyzing various disease conditions and molecules, it does not teach how to make a catalytic antibody that will attach "a label to said target molecule". Nowhere is this shown to be operable nor what method and/or hapten to use to make this catalytic antibody. The production of catalytic as opposed to non-catalytic antibodies is not predictable but rather requires some inventive contribution by applicant such as the specific antigen to use and/or the specific method to use.

Janda, et. al. (U-1), Schultz (D), Sinha, et al. (E) and Yu, et al. (V-1) are cited in this regard. In Janda, catalytic antibodies were raised against hapten (1) and it was found that substrates with the greatest homology to the hapten (2 and 3) were not hydrolyzed appreciably by the antibody, whereas substrates that had less homology to the hapten (4-6) were hydrolyzed. In Schultz, a catalytic antibody raised against a mixture of diastereomers of a hapten (I) catalyzed the cleavage of a homologous substrate (II) but only the D diastereomer, not the L diastereomer, even though the hapten was a mixture of diastereomers. In Sinha, et al. the hapten used to make the antibodies (Fig. 4) had essentially no resemblance to the reactants or products of the reaction catalyzed (Fig. 1). In Yu, et al. twenty-nine different antibodies were made against a close analog of a substrate and none of

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them had catalytic activity (see column 2, page 340). As discussed by Tawfik, et al. (W-1) on pages 91-92, most catalytic antibody activity (in 1994) "is still very modest" compared with enzymes. "[T]he nature of all of the reported antibody-catalyzed reactions is such that they proceed with measurable rates even in the absence of any catalyst". "Most of the antibody catalyzed hydrolytic reactions involve esters, and in particular phenyl esters (that are relatively labile)....The hydrolysis of amides, that are orders of magnitude more stable than esters, was demonstrated only when activated amide substrates were used or when intramolecular deamidation could occur...or by utilizing the chemical reactivity of a metal complex". Applicant have not demonstrate that catalytic antibodies can be made to any and all target molecules and "labels" to attach the label to the target molecule. Nor is there any teaching in the specification of any prior art that would lead one to make such antibodies. Therefore it is maintained that undue experimentation would be required to practice the claimed invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546, 547 and used in determining proper scope in numerous later decisions such as *In re Wands*, 8 USPQ2d 1400, 1404. These factors are (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in that art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. In the instant application there is essentially no guidance given as to what happen or process to use to make the catalytic antibodies (2) and there are no examples given (3). As stated *supra*, there is apparently no guidance given in the prior art to make these particular catalytic antibodies

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(5) and the breadth of the claims is broad (8). Therefore, it is maintained that undue experimentation would be required to practice the invention with the guidance given in the instant specification.

Claims 17-20, 23 and 26 have been amended to be drawn to a "non-naturally occurring enzyme". The specification does not teach nor enable one of ordinary skill in the art to make the "non-naturally occurring enzyme" of the instant claims. Other than the general recitations referred to *supra*, it is not taught how a naturally occurring enzyme could be modified to make a non-naturally occurring one having the attributes of the instant claims. There are no examples given in the specification of such an enzyme having been made and it is maintained that undue experimentation would have been required to make such an enzyme for many of the reasons outlined *supra*.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant argues that the enablement prong of 35 USC § 112 first paragraph is separate and distinct from the written description requirement and that "[i]t appears that the Examiner is confusing the 'written description' and 'enablement' prongs". The examiner is aware that the two requirements are separate and distinct and that is why he make two separate rejections.

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He is not confusing the two requirements. It is then argued that "the function of the written description requirement is to ensure that...inventors...had possession, as of the filing date of the application...[and that] how the specification accomplishes this is not material". Next the examiner's attention is drawn to Example 16 in the Written Description Guidelines. This example deals with non-catalytic antibodies and states that where the antigen is disclosed, an antibody made to that antigen would meet the requirement of 35 USC § 112 first paragraph. This does not state anything about catalytic antibodies. As previously stated and as stated in the specification, catalytic antibodies are generally made using transition states to the reaction to be catalyzed. Some transition state analogs or other haptens will produce catalytic antibodies and some will not, as discussed *supra*. This is not predictable beforehand. The instant claims are drawn to attaching any label to a target molecule consisting of any "protein, peptide, nucleic acid, carbohydrate, cell, subcellular particle, virus, steroid, [and] lipid". While a particular target molecule might be known and a particular label might be known, the claims are not limited to any particular ones. The specification certainly does not teach any hapten that will produce a catalytic antibody, so that even if the particular target molecule and label were known, the particular hapten that would produce a catalytic antibody that would attach a label to the target molecule is not taught in the specification. Therefore it is maintained that one of ordinary skill in the art reading the instant specification would not conclude that applicant had possession of the claimed invention. Similarly, it is maintained that one of ordinary skill in the art would conclude that applicant did not have possession of the "non-naturally occurring enzyme" of claims 17-20, 23 and 26.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

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<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
January 23, 2006